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Substitute for form 1449A/PTO	Con	Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/751,056		
۱ ه۱	Filing Date	January 2, 2004		
JAN 2 9 2010 (1)	First Named Inventor	Gerianne Tringali DiPiano		
<u>"</u> "	Group Art Unit	1628		
\$/	Examiner Name	Jennifer M. Kim		
SKBabeman 1 of 9	Attorney Docket Number	FEM 104		

			· ·	U.S. PATENT DOCU	MENTS	
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,921,636		Zaffaroni	11-25-1975	
		3,927,216		Witkowski, et al.	12-16-1975	
		4,081,533		Cheesman	03-28-1978	
		4,107,288		Oppenheim, et al.	08-15-1978	
		4,272,398		Jaffe	06-09-1981	
		4,286,587		Wong	09-01-1981	
		4,291,028		Vorys	09-22-1981	
		4,292,315		Vorys	09-29-1981	
		4,391,797		Folkman, et al.	07-05-1983	
		4,524,359		Champagne	06-18-1985	
		4,525,340		Lange, et al.	06-25-1985	
		4,588,724		Greenway, III, et al.	05-13-1986	
		4,591,496		Cohen, et al.,	05-27-1986	
		4,673,405		Guittard, et al.	06-16-1987	
		4,756,907		Beck, et al.	07-12-1988	
		4,762,717		Crowly, Jr.	08-09-1988	
		4,861,627		Mathiowitz, et al.	08-29-1989	

	•			F	OREIGN PATENT DOCUMEN	TS		
Examiner Initials*	Cite No.1		Foreign Patent Docum	nent	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office.3	Number⁴	Kind Code <sup>5</sup> (if known)	]			
		EP	0 501 056		Igarashi, et al.	09-02-1992		
		EP	0 566 135		Takeda Chemical Industries	10-20-1993		
		GB	767 824		Organon Labor Ltd.	02-06-1957	<u></u>	

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Sheet	2	of	9	Attorney Docket Number	FEM 104		

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		4,873,092		Azuma, et al	10-10-1989	
		4,919,939		Baker	04-24-1990	
		4,965,128		Greidanus, et al.	10-23-1990	
	•	4,997,653		lgarashi, et al.	03-05-1991	
		5,057,317		lida	10-15-1991	
		5,091,185		Castillo, et al.	02-25-1992	
		5,130,137		Crowley, Jr.	07-14-1992	
		5,145,684		Liversidge, et al.	09-08-1992	
		5,156,851		Castillo, et al.	10-20-1992	
		5,194,259		Soudant, et al.	03-16-1993	
		5,324,522		Krenning, et al.	06-28-1994	
		5,330,768		Park, et al.	07-19-1994	
		5,340,585		Pike, et al.	08-23-1994	
		5,359,030		Ekwuribe	10-25-1994	
		5,362,720		Labrie	11-08-1994	
****		5,413,797		Khan, et al.	05-09-1995	

				F	OREIGN PATENT DOCUMEN	ITS		
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		Office.3	Number⁴	Kind Code <sup>5</sup> (if known)	1			
	·	PCT	WO 95/07071		Edko Trading and Representation Co.	03-16-1995		
		PCT	WO 95/31973		Eastman Kodak Co.	11-30-1995		
		PCT	WO 95/31974		Eastman Kodak Co.	11-30-1995		

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				Group Art Unit	1628		
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		Number Kind Code (if known			
		5,417,982	Modi	05-23-1995	
		5,434,146	Labrie	07-18-1995	
		5,438,040	Ekwuribe	08-01-1995	
		5,472,704	Santus, et al.	12-05-1995	
-		5,482,925	Hutsell	01-09-1996	
		5,482,927	Maniar, et al.	01-09-1996	
		5,494,047	Van Os	02-27-1996	
		5,510,118	Bosch, et al.	04-23-1996	
		5,536,499	Znaiden, et al.	07-16-1996	
		5,552,160	Liversidge, et al.	09-03-1996	
		5,633,011	Dong, et al.	05-27-1997	
		5,643,604	Angeles Uribe, et al.	07-01-1997	
		5,651,976	Price, et al.	07-29-1997	
		5,705,170	Kong, et al.	01-06-1998	
		5,778,894	Dorogi, et al.	07-14-1998	
		5,789,442	Garfield, et al.	08-04-1998	
		5,843,509	Calvo Salve, et al.	12-01-1998	
		5,945,109	Schmidt, et al.	08-13-1999	

					OREIGN PATENT DOCUMEN	113		
Examiner Initials*	Cite No. <sup>1</sup>	.		ıment	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T°
				Office.3	Number⁴	Kind Code <sup>5</sup> (if known)		
		PCT	WO 96/00567		Eastman Kodak Co.	01-11-1996		
		PCT	WO 96/25150		Nanosystems LLC	08-22-1996		

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				First Named Inventor	Gerianne Tringali DiPiano		
				Group Art Unit	1628		
				Examiner Name	Jennifer M. Kim		
	1	of	. 9	Attorney Docket Number	FEM 104		

			U.S. PATENT DOCU	MENTS	
Examiner Initials*	Cite No.1	US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code (if known			
		6,071,526	Schmidt, et al.	06-06-2000	
		6,087,351	Nyce	07-11-2000	
		6,358,539	Murad	03-19-2002	
		6,436,428	Mahashabde, et al.	08-20-2002	
		6,517,864	Orup Jacobsen, et al	02-11-2003	
		6,743,441	Sanders, et al.	06-01-2004	
		6,908,623	Deaver, et al.	06-21-2005	
		2002/0150605	Yui, et al.	10-17-2002	
_		2003/0109507	Franke, et al.	06-12-2003	
		2003/0143278	DiPiano, et al.	07-31-2003	
		2003/0175329	Azarnoff, et al.	09-18-2003	
		2004/0002503	Chang, et al.	01-01-2004	
		2005/0101579	Shippen	05-12-2005	
		2008/0153789	Dmowski, et al.	06-26-2008	
		2008/0299207	Martin	12-04-2008	
		12/497,865	DiPiano, et al.	07-06-2009	

				F	OREIGN PATENT DOCUMEN	NTS		
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		PCT	WO 96/37232		Universidade de Santiago d	de 11-28-1996		
					Compostela (ES)			
		PCT	WO 98/11888		American Home Prod.	03-26-1998		
		PCT	WO 99/24041		Cellegy Pharma Inc.	05-20-1999		

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Sheet	5	of	9	Attorney Docket Number	FEM 104			

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		PCT	WO 02/17926		Unimed Pharma Inc.	03-07-2002			
		PCT	WO 03/039553		Pharmacia Corporation	05-15-2003			
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		OTHER ART NON PATENT LITERATURE DOCUMENTS	<del>2</del>
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		AKIO, "Danazol Suppository", Patent Abstracts of Japan 15(263): (C-0847) (1991).	
		ANDERSON, et al., "Once daily controlled versus immediate release oxybutynin chloride for urge urinary incontinence. OROS Oxybutynin Study Group," <i>J. Urol.</i> 161: 1809-1812 (1999).	
		BARNHART, et al., "Distribution of a spermicide containing Nonoxynol-9 in the vaginal canal and the upper female reproductive tract", <i>Hum Reprod</i> ,.16(6):1151-4 (2001).	
		BENITA, et al., "Characterization of drug-loaded poly(d,l-lactide) microspheres," J Pharm Sci 73(12): 1721-1724 (1984).	
		BRAUN, et al., "Effect of danazol <i>in vitro</i> and <i>in vivo</i> on monocyte-mediated enhancement of endometrial cell proliferation in women with endometriosis," <i>Fertility and Sterility</i> 62(1): 89-95 (1994).	
		BRENDLER, et al., "Topical oxybutynin chloride for relaxation of dysfunctional bladders," J. Urol. 141(6): 1350-52 (1989).	
		BUYSE, et al., "Intravesical oxybutynin for neurogenic bladder dysfunction: less systemic side effects due to reduced first pass metabolism," <i>J. Urol.</i> 160: 892-896 (1998).	
		CICINELLI, et al., "First uterine pass effect is observed when estradiol is placed in the upper buy not lower third of the vagina", Fertility and Steriility, 81(5):1414-1416 (2004).	
-		COMER & GOA, "Extended-release oxybutynin," <i>Drugs Aging</i> 16: 149-155 (2000).	
		DAS NEVES, et al., "Gels as vaginal drug delivery systems", Int. J. Pharm. 2:318(1-2):1-14 (2006) Epub 2006 Mar 17.	
,		DE ZIEGLER, et al., "Administration non-orale de la progestérone: Expériences et avenir de la voie transvaginale," Rev. Med. Suisse Romande pp. 13-28 (1994) (with English abstract).	
		FARQUHAR, et al., "Management of dysfunctional uterine bleeding," Drugs 44(4): 378-384 (1992).	

Examiner's	·	Date Considered
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	0:1-	OTHER ART NON PATENT LITERATURE DOCUMENTS	
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		FEMMEPHARMA, "FP1096-001 Executive Summary," (2004).	
		FINNIN and MORGAN, "Transdermal penetration enhancers: applications, limitations, and potential", <i>J. Pharm. Sci.</i> , 88(10):955-8 (1999).	
		GERAGHTY, et al., "The in vitro release of some antimuscarinic drugs from monoolein/water lyotropic crystalline gels," <i>Pharm. Res.</i> 13(8): 1265- 1271 (1996).	
		GOLDENBERG, "An extended-release formulation of oxybutynin chloride for the treatment of overactive urinary bladder," Clin. Ther. 21(4): 634-642 (1999).	-
		GUPTA & SATHYAN, "Pharmacokinetics of an oral once-a-day controlled-release oxybutynin formulation compared with immediate-release oxybutynin," <i>J. Clin. Pharmacol.</i> 39: 289-296 (1999).	
		GUERRIERO, et al., "Influence of vaginal danazol on uterine and brain perfusion during hormonal replacement therapy", Menopause, 8(6); 424-428 (2001) (abstract only).	
		HULL, et al., "Endometriosis: An enigmatic disease," <i>J Women's Health</i> 5(2): 111-120 (1996).	
		IGARASHI, "A new therapy for pelvic endometriosis and uterien adenomysosis: Local effect of vaginal and intrauterine danazol application," <i>Asia-Oceania J. Obstet. Gynaecol.</i> 16(1): 1-12 (1990).	
·		LIM, et al., "Microencapsulation of living cells and tissues," J Pharm. Sci. 70(4): 351-354 (1981).	
		LIVERSIDGE, et al., "Particle size reduction for improvement of oral bioavailability of hydrophobic drugs: I. Absolute oral bioavailability of nanocrystalline danazol in beagle dogs", Int J Pharm., 125:91-97 (1995).	
		LOBO, et al., "Vaginal route paradox: A direct transport to the uterus," <u>Symposium: The First Uterine Pass Effect</u> , Wyeth-Ayerst International, Inc. (1995).	
		MASSAD, et al., "The pharmacokinetics of intravesical and oral oxybutynin chloride," J. Urol. 148: 595-597 (1992).	

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		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery system," <i>Scanning Microscopy</i> 4(2): 329-340 (1990).	
		MATHIOWITZ, et al., "Novel microcapsules for delivery systems," Reactive Polymers 6: 275-283 (1987).	
70.31		MATHIOWITZ, et al., "Polyanhydride microshperes as drug carriers I. Hot-melt microencapsulation," <i>J Controlled Release</i> 5:13-22 (1987).	
	-	MATHIOWITZ, et al., "Polyanhydride microspheres as drug carriers. II. Microencapsualtion by solvent removal," <i>J Appl. Polymer Sci.</i> 35: 755-774 (1988).	
		MIZUTANI, et al., "Danazol concentration in ovary, uterus, and serum and their effect on the hypothalamic-pituitary-ovarian axis during vaginal administration of a danazol suppository," Feritility and Sterility 63(6): 1184-1189 (1995).	
		Physicians' Desk Reference, Consult 1994 Supplements for Revisions, pp. 1372-1375.	
		RAMJEE, et al., "Acceptability of Carraguard, a candidate microbicide and methyl cellulose placebo vaginal gels among HIV-positive women and men in Durban, South Africa", AIDS Res Ther. 4:20 pp.1-10 (2007).	
		SAITO, et al., "Treatment of overactive bladder with modified intravesical oxybutynin chloride," Neurol. Urodyn. 19: 683-688 (2000).	
		SALIB, et al., "Utilization of sodium alginate in drug microencapsulation," Pharmazeutische Industrie 40(11A): 1230-1234 (1978).	
		SCHRÖDER, et al., "Absorption of oxybutinin from vaginal inserts: drug blood levels and the response of the rabbit bladder," Urology 56(6): 1063-1067 (2000).	
		SPOONER, Classification of Side Effects to Danazol Therapy, Winthrop Laboratories, Surrey, England.	

Examiner's		Date Considered 04/40/2040
Signature	/Jennifer Kim/	04/19/2010

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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STA	TEME	TION DISCLOSURE NT BY APPLICANT  ny sheets as necessary)	Application Number	10/751,056
	(use as ma	ny sneets as necessary)	Filing Date	January 2, 2004
			First Named Inventor	Gerianne Tringali DiPiano
		•	Group Art Unit	1628
			Examiner Name	Jennifer M. Kim
9	of	9	Attorney Docket Number	FEM 104

		OTHER ART NON PATENT LITERATURE DOCUMENTS	T²				
Examiner's Initials*	Cite No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					
		"Sultrin," Physicians' Desk Reference, 51st ed., pp. 1941 (1997).					
		TAKEBAYASHI, et al., "Danazol suspension injected into the uterine cervix of patients with adenomyosis and myoma. Preliminary study", <i>Gynecol. Obstet. Invest.</i> , 39(3):207-11 (1995) (abstract only).					
		"Terazol 7," Physicians' Desk Reference, 51st ed., pp. 1943 (1997).					
		The First Uterine Pass Effect – A new finding for new options in progesterone therapy, West-Ayerst Internation, Inc., pp 1-2 (1995).					
		THÜROFF, et al., "Randomized, double-blind, multicenter trial on treatment of frequency, urgency and incontinence related to detrusor hyperactivity: oxybutynin versus propantheline versus placebo," <i>J. Urol.</i> 145: 813-816 (1991).					
		VERSI, et al., "Dry mouth with conventional and controlled-release oxybutynin in urinary incontinence," Obstet Gynecol. 95(5): 718-721 (2000).					
		WAGNER, et al., "The novel progesterone receptor antagonists RTI 3021-012 and RTI 3021-022 exhibit complex glucocorticoid receptor antagonist activities: implications for the development of dissociated antiprogestins", Endocrinology, 140(3):1449-58 (1999).					
		WELLBERY, et al., "Diagnosis and treatment of endometriosis", Am. Fam. Physician, 60:1753-68 (1999).					
		WOLTHERS KLUWER HEALTH, INC., "Summary Review: Oxybutynin Chloride 10 % Gel", Wolthers Kluwer Health, Inc., (2009).					
		YAMASHITA, et al., "Immunohistochemical determination of endometrial progesterone receptor (PR) content after intrauterine infusion of danazol in rabbits", Nippon Naibunpi Gakkai Zasshi, 69(10):1044-1050 (1993) (abstract only).					
		ZHANG, et al., "Synthesis and progesterone receptor antagonist activities of 6-aryl benzimidazolones and benzothiazolones", Bioorg. Med. Chem. Lett., 11(20):2747-50 (2001).					

Examiner's Signature	/Jennifer Kim/	Date Considered	04/19/2010

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